

General Assembly

Substitute Bill No. 6791

January Session, 2005

____HB06791PRI___031805____

AN ACT IMPLEMENTING THE RECOMMENDATIONS OF THE LEGISLATIVE PROGRAM REVIEW AND INVESTIGATIONS COMMITTEE RELATIVE TO PHARMACY REGULATION.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (Effective from passage) Not later than January 1, 2 2006, the Department of Consumer Protection shall submit to the joint 3 standing committee of the General Assembly having cognizance of matters relating to general law, in accordance with the provisions of 4 5 section 11-4a of the general statutes, a report that summarizes the 6 activities of the department related to the regulation of the Pharmacy Practice Act, the federal Food, Drug and Cosmetic Act and the state 8 controlled substance act. Such report shall include, but not be limited 9 to, information on the number and type of pharmacy inspections and 10 investigations conducted by the Department of Consumer Protection 11 concerning: (1) The number of investigations conducted, (2) the reason 12 for each investigation, (3) the subject matter of each investigation, (4) 13 the outcome of each investigation, (5) any action taken by any board of 14 the Department of Public Health or the Commission of Pharmacy, (6) 15 any action taken by the Commissioner of Consumer Protection on a 16 practitioner's controlled substance registration, and (7) the timeline for 17 such investigation beginning with the opening of such case 18 investigation and ending with the final board or commission action. 19 Such report shall be updated and resubmitted to the said joint standing

committee on January 1, 2007, and on January 1, 2008.

- 21 Sec. 2. (NEW) (Effective from passage) Not later than January 1, 2006,
- 22 in accordance with the provisions of section 11-4a of the general
- 23 statutes, The University of Connecticut Health Center shall submit a
- 24 report to the Legislative Program Review and Investigations
- 25 Committee that identifies deficiencies in the administration of drugs in
- 26 correctional facilities found within the previous calendar year. Such
- 27 report shall be updated on January 1, 2007, and on January 1, 2008.
- 28 Sec. 3. Section 20-577 of the general statutes is repealed and the
- 29 following is substituted in lieu thereof (*Effective from passage*):
- 30 (a) The commissioner shall employ inspectors whose duty it shall be
- 31 to inspect all pharmacies and other places in which drugs and devices
- 32 are or may be dispensed or retailed, and to report any violations of
- 33 sections 20-570 to 20-630, inclusive, or other laws relating to drugs and
- 34 devices and violations of laws regarding pharmacy licenses, nonlegend
- 35 drug permits, licenses of pharmacists and supervision of pharmacy
- 36 interns and pharmacy technicians.
- 37 (b) The commissioner shall inspect correctional or juvenile training
- 38 institutions and care-giving institutions throughout the state with
- respect to the handling of drugs, shall report violations of law and 39
- 40 make recommendations for improvements in procedures to the
- 41 authority responsible for the operation of the institution and shall take
- 42 such other steps as may be necessary to ensure proper and adequate
- 43 storage, handling and administration of drugs in such institutions. The
- 44 commissioner may also inspect dispensing outpatient facilities and
- 45 institutional pharmacies and take such steps as the commissioner
- 46 considers appropriate to correct deficiencies found in such facilities or
- 47 institutional pharmacies with respect to their operation.
- 48 (c) The commissioner shall inspect each retail pharmacy not less
- 49 than once every four years and shall develop a methodology to sample
- 50 prescriptions dispensed by retail pharmacies for compliance with state
- 51 laws concerning the dispensing of prescriptions. Such methodology

- 52 <u>shall be based on the number of prescriptions received by such retail</u> 53 pharmacies.
 - Sec. 4. Section 21a-262 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):
- 56 (a) The Commissioner of Consumer Protection may receive, take 57 into custody or destroy excess or undesired controlled substances and 58 may in his discretion deliver, upon application, to any hospital, 59 laboratory, incorporated college, scientific institution or any state or 60 municipal agency or institution not operated for private gain, any 61 controlled substances that have come into his custody by authority of 62 this section. In the case of a care-giving or correctional or juvenile 63 training institution having an institutional pharmacy, 64 Commissioner of Consumer Protection shall deliver such controlled 65 substances only to the licensed pharmacist in charge of such 66 pharmacy. The Commissioner of Consumer Protection may receive 67 and take into custody excess or undesired controlled substances from pharmacists, manufacturers and wholesalers or any other registrant. 68 69 Said commissioner shall keep a full and complete record of all 70 substances received and of all substances disposed of, showing the 71 exact kinds, quantities and forms of such substances, the persons from 72 whom received and to whom delivered, by whose authority received, 73 delivered and destroyed, and the dates of the receipt, disposal or 74 destruction. Controlled substances and preparations shall at all times 75 be properly safeguarded and securely kept. Minimum security and 76 safeguard standards for the storage, manufacture, sale or distribution 77 of all controlled substances shall be established by regulations adopted 78 hereunder. Controlled substances seized or held as contraband or 79 controlled substances, the title to which cannot be resolved, which 80 controlled substances are not held by law enforcement agencies or 81 court officials as evidence in criminal proceedings, shall be, upon the 82 order of the court, destroyed by the seizing authority or delivered to 83 the Commissioner of Consumer Protection as soon as possible upon 84 resolution of the case or upon ascertaining the status of the unclaimed 85 substance. The agent of the Commissioner of Consumer Protection

54

shall issue a receipt for all such substance obtained. Any loss, destruction or theft of controlled substances shall be reported by a registrant within seventy-two hours to the Commissioner of Consumer Protection as follows: (1) Where, through breakage of the container or other accident, otherwise than in transit, controlled substances are lost or destroyed, the person having title thereto shall make a signed statement as to the kinds and quantities of controlled substances lost or destroyed and the circumstances involved, and immediately forward the statement to the Commissioner of Consumer Protection. A copy of such statement shall be retained by the registrant; (2) where controlled substances are lost by theft, or otherwise lost or destroyed in transit, the consignee shall, immediately upon ascertainment of the occurrence, file with the Commissioner of Consumer Protection a signed statement of the facts, including a list of the controlled substances stolen, lost or destroyed and documentary evidence that the local authorities were notified. A copy of the statement shall be retained by the registrant. As used in this section, "care-giving institution", "correctional or juvenile training institution", "institutional pharmacy" and "pharmacist" shall have the same meaning as used in section 20-571.

(b) For each long-term care facility, two or more of the following persons may jointly dispose of excess stock of controlled substances: A nursing home administrator, a pharmacist consultant, a director of nursing services or an assistant director of nursing services. Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a separate log and on a form prescribed by the department.

(c) For each outpatient surgical facility, as defined in section 19a-493b, two or more of the following persons may jointly dispose of excess stock of controlled substances: An administrator, a clinical director or chief of staff, or a nursing supervisor. Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a

86 87

88

89

90

91

92

93 94

95

96

97

98

99

100

101

102

103

104

105

106

107

108

109 110

111

112

113

114

115

116

117

120 separate log and on a form prescribed by the department.

- Sec. 5. (NEW) (Effective from passage) Not less than once every three months, the Department of Consumer Protection shall compile a regulatory action report that contains information regarding: (1) Any disciplinary action taken by the department against any person with a controlled substance registration, and (2) any sanction by the Commission of Pharmacy against a pharmacy or pharmacist. Such report shall contain the reasons for any such action or sanction and shall be posted on the web site of the department.
- 129 Sec. 6. (NEW) (Effective from passage) (a) On and after October 1, 130 2005, any person licensed as a pharmacist under part II of chapter 400j 131 of the general statutes may administer influenza vaccine to an adult, 132 provided the administration is conducted pursuant to the order of a 133 licensed health care provider and in accordance with the regulations 134 established pursuant to subsection (b) of this section.
 - (b) Not later than September 1, 2005, the Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health and the Commission of Pharmacy, shall adopt regulations, in accordance with chapter 54 of the general statutes, to implement the provisions of this section. Such regulations shall (1) require any pharmacist who administers influenza vaccine to an adult pursuant to this section to successfully complete an immunization training program for pharmacists; (2) define the basic requirements of such training program, which shall include training and instruction in preadministration education and screening, vaccine storage and handling, subcutaneous and intramuscular injections, recordkeeping, vaccine safety, cardiopulmonary resuscitation, basic cardiac life support and adverse event reporting; (3) identify qualifying training programs, which are accredited by the National Centers for Disease Control Prevention, the Accreditation Council for Pharmacy Education or other appropriate national accrediting body; and (4) establish a system of control and reporting.

121

122

123

124

125

126

127

128

135

136

137

138

139

140

141

142

143

144

145

146

147

148

149

150

(c) For purposes of this section, "adult" means an individual who has attained the age of eighteen years.

This act shall take effect as follows and shall amend the following sections:		
Section 1	from passage	New section
Sec. 2	from passage	New section
Sec. 3	from passage	20-577
Sec. 4	from passage	21a-262
Sec. 5	from passage	New section
Sec. 6	from passage	New section

PRI Joint Favorable Subst.